## **CLAIMS**

- 1. A production process for a polymeric micelle charged therein with a water-scarcely soluble drug, comprising the steps of:
- (A) dissolving a water-scarcely soluble drug and a block copolymer having a hydrophilic segment and a hydrophobic segment in a water non-miscible organic solvent to prepare an organic solution,
- (B) mixing the resulting organic solution with an aqueous medium to form an oil-in-water (O/W) type emulsion,
- (C) vaporizing and removing the above organic solvent from the resulting emulsion to form a polymeric micelle solution charged therein with the above drug, and
- (D) subjecting the resulting polymeric micelle solution, if necessary, to supersonic treatment and ultrafiltration treatment.
- 2. The production process as described in claim 1, wherein the hydrophilic segment is a segment comprising at least one selected from the group consisting of poly(ethylene oxide), poly(malic acid), poly(saccharide), poly(acrylic acid), poly(vinyl alcohol) and poly(vinyl-pyrrolidone).
- 3. The production process as described in claim 1 or 2, wherein the hydrophobic segment is a segment comprising at least one selected from the group consisting of poly( $\beta$ -benzyl aspartate), poly( $\gamma$ -benzyl glutamate), poly( $\beta$ -alkyl aspartate), poly(lactide), poly( $\epsilon$ -caprolactone), poly( $\delta$ -valerolactone), poly( $\gamma$ -butyrolactone) and poly( $\alpha$ -amino acid).
- 4. The production process as described in claim 1, wherein the hydrophilic segment comprises poly(ethylene oxide), and the hydrophobic segment is selected from the group consisting of poly- $(\beta$ -benzyl aspartate), poly( $\gamma$ -benzyl glutamate), poly( $\beta$ -benzyl aspartate-co-aspartic acid) and poly( $\gamma$ -benzyl glutamate-co-glutamic acid).
- 5. The production process as described in claim 1, wherein the block copolymer is represented by the following Formula (I) or

(II):

or

[wherein  $R_1$  and  $R_3$  each represent a hydrogen atom or a lower alkyl group;  $R_2$  represents a hydrogen atom, a saturated or unsaturated  $C_1$  to  $C_{29}$  aliphatic carbonyl group or an arylcarbonyl group;  $R_4$  represents a hydroxyl group, a saturated or unsaturated  $C_1$  to  $C_{30}$  aliphatic oxy group or an aryl-lower alkyloxy group;  $L_1$  represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a  $C_1$  to  $C_4$  alkylene group);  $L_2$  represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a  $C_1$  to  $C_4$  alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 3: 1 to 0: 100; and x and y each are present at random].

- 6. The production process as described in claim 5, wherein x to y in Formula (I) or (II) falls in a range of 7:3 to 1:3.
- 7. The production process as described in any of claims 1 to 6, wherein the drug and the block copolymer are used in a weight ratio of 1:10 to 3:10.
- 8. The production process as described in any of claims 1 to 7, wherein the water non-miscible organic solvent is at least one selected from the group consisting of chloroform, methylene chloride, toluene, xylene and n-hexane.
- 9. The production process as described in any of claims 1 to 8, wherein the drug is selected from the group consisting of paclitaxel,

docetaxel and camptothecin and topotecan.

10. A composition comprising a polymeric micelle originating in a block copolymer charged therein with a drug, wherein the drug is a water-scarcely soluble drug; the block copolymer is represented by the following Formula (I) or (II):

$$R_{1} \leftarrow OCH_{2}CH_{2} \rightarrow \Pi L_{1} - \left( (COCHNH)_{X} \cdot (COCHNH)_{y} \rightarrow R_{2} \right)$$

$$CH_{2}COOH \quad CH_{2}COOCH_{2}$$

$$(I)$$

or

$$R_{3} = (OCH_{2}CH_{2})_{\overline{D}} L_{2} = \left( (NHCHCO)_{X} \cdot (NHCHCO)_{y} \right) R_{4}$$

$$CH_{2}COOH \qquad CH_{2}COOCH_{2}$$
(II)

[wherein  $R_1$  and  $R_3$  each represent a hydrogen atom or a lower alkyl group;  $R_2$  represents a hydrogen atom, a saturated or unsaturated  $C_1$  to  $C_{29}$  aliphatic carbonyl group or an arylcarbonyl group;  $R_4$  represents a hydroxyl group, a saturated or unsaturated  $C_1$  to  $C_{30}$  aliphatic oxy group or an aryl-lower alkyloxy group;  $L_1$  represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a  $C_1$  to  $C_4$  alkylene group);  $L_2$  represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a  $C_1$  to  $C_4$  alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 7: 3 to 1: 3; and x and y each are present at random]; a micelle solution prepared by dissolving or dispersing the above micelle in water can stably be maintained in a drug concentration of at least 3 mg per ml of the solution.

- 11. The composition as described in claim 10, wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and topotecan.
- 12. The composition as described in claim 10, wherein the drug

is paclitaxel and an analogue thereof.